

DETAILED ACTION

1. The amendment filed on November 6, 2009 has been received and considered. By this amendment, claims 33, 34, 36, 38, 40-45, 47, 49, 51-53, 55, 57, 59, and 60 are amended, claims 37, 39, 46, 48, 56, and 58 are cancelled, claim 61 is added, and claims 33-36, 38, 40-45, 47, 49-55, 57, and 59-61 are now pending in the application.

Claim Objections

2. Claims 33-36, 38, 40-45, 47, 49-55, 57, 59, and 60 are objected to because of the following informalities:

- a. In claim 36, lines 3-4, "comparing a a T-wave" should read "comparing a T-wave";
- b. In claim 41, lines 4-5, the phrase "a pacing interval that the ventricular pacing pulse is delivered at" is grammatically improper. It is suggested that such a phrase be rewritten to read "a pacing interval at which the ventricular pacing pulse is delivered";
- c. In claim 51, lines 4-5, the phrase "modulate a pacing interval modulates a pacing interval that the ventricular pacing pulse is delivered at" repeats "modulate a pacing interval" and is grammatically improper. It is suggested that such a phrase be rewritten to read "modulate a pacing interval at which the ventricular pacing pulse is delivered";
- d. The reference to claim 52 in claim 53 has been deleted and as such, claim 53 refers to "the computer-readable medium of claim" but fails to indicate on

which claim it depends. For the purposes of this communication, the Examiner believes that claim 53 should depend on independent claim 51;

e. In claim 60, lines 3-4, the phrase “a pacing interval that the ventricular pacing pulse is delivered at” is grammatically improper. It is suggested that such a phrase be rewritten to read “a pacing interval at which the ventricular pacing pulse is delivered”;

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 33-36, 38, 40-45, 47, 49-55, 57, 59, and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 33 recites the limitation “wherein modulating the pacing interval comprises randomly altering a delivery time of the pacing pulses” in lines 2-3. It is unclear how such an alteration could be truly random if it is always performed when the pacing interval is modulated. Furthermore, a random alteration may be an unintentional, or accidental, alteration, which may or may not occur according to the claim. Therefore, it is not clear from the claim exactly how the pacing interval is modulated.

6. Claim 36 recites the limitation “wherein detecting whether an autonomous intrinsic signal component is present within the heart comprises comparing a T-wave”

in lines 1-4. However, the claim fails to describe how or to what such a T-wave should be compared. As such, it is unclear how such a step is to be performed.

7. Claim 41 recites the limitation "determining if the same morphological characteristic of the ventricular signal response to the delivered pacing pulse deviates enough from the morphological characteristic of the past ventricular signal to exceed a threshold" in lines 16-19. Neither the claim, nor the specification, indicate what would be a sufficient deviation for the pacing pulse from the morphological characteristic of the past ventricular signal to exceed a threshold. The claim and the specification both fail to describe such a threshold or suggest an appropriate value for such a threshold. As such, it is unclear what would constitute enough of a deviation to satisfy such claim limitations.

8. Claim 42 recites the limitation "wherein the processor modulates the pacing interval by randomly altering a delivery time of the pacing pulses" in lines 1-3. It is unclear how such an alteration could be truly random if it is always performed when the pacing interval is modulated.

9. Claim 45 recites the limitation "wherein the processor detects whether an autonomous intrinsic signal component is present by comparing a T-wave" in lines 1-4. However, the claim fails to describe how or to what such a T-wave should be compared. As such, it is unclear how such a step is to be performed.

10. Claim 51 recites the limitation "determining if the same morphological characteristic of the ventricular signal response to the delivered pacing pulse deviates enough from the morphological characteristic of the past ventricular signal to exceed a

threshold" in lines 20-22. Neither the claim, nor the specification, indicate what would be a sufficient deviation for the pacing pulse from the morphological characteristic of the past ventricular signal to exceed a threshold. The claim and the specification both fail to describe such a threshold or suggest an appropriate value for such a threshold. As such, it is unclear what would constitute enough of a deviation to satisfy such claim limitations.

11. Claim 52 recites the limitation "instructions to cause the processor to modulate the pacing interval by randomly altering a delivery time of the pacing pulses" in lines 1-3. It is unclear how such an alteration could be truly random if it is always performed when the pacing interval is modulated.

12. Claim 55 recites the limitation "wherein the instructions cause the processor to detect whether an autonomous intrinsic signal component is present within the heart by comparing a T-wave" in lines 1-4. However, the claim fails to describe how or to what such a T-wave should be compared. As such, it is unclear how such a step is to be performed.

13. Claim 60 recites the limitation "determining if the same morphological characteristic of the ventricular signal response to the delivered pacing pulse deviates enough from the morphological characteristic of the past ventricular signal to exceed a threshold" in lines 17-19. Neither the claim, nor the specification, indicate what would be a sufficient deviation for the pacing pulse from the morphological characteristic of the past ventricular signal to exceed a threshold. The claim and the specification both fail to describe such a threshold or suggest an appropriate value for such a threshold. As

such, it is unclear what would constitute enough of a deviation to satisfy such claim limitations.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 33, 35, 36, 38, 40-42, 44, 45, 47, 49-52, 54, 55, 57, and 59-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Dam. Regarding claims 33, 36, 38, 41, 42, 44-47, 51, 52, 55, 57, 60, and 61, Van Dam discloses ventricular pacing electrodes 28 and 29 at the distal end of ventricular pacing lead 18 which are capable of delivering a pacing pulse to a ventricle of the heart (see col. 4, ln. 19-21), detects intrinsic ventricular activity (see col. 11, ln. 21-22 and col. 3, ln. 58-60), and extends a pacing interval between pacing pulses based on the detection of intrinsic ventricular activity (see col. 1, ln. 7-11). Attention is directed to Figure 6 where at decision block 200 it is determined whether an intrinsic Vevent occurred or a paced Vevent. When it is determined that a paced Vevent occurred, the flow progresses to block 215 where intrinsic ventricular activity is detected and further to block 210 where the pacing interval is extended based on the detection of intrinsic ventricular activity (see Figures 6 and 8 and col. 3, ln. 58-60). Furthermore, Van Dam discloses that in

order to detect intrinsic ventricular activity within the heart, a past ventricular signal is compared with the current ventricular signal (see col. 1, ln. 56-59), that a past ventricular signal may be a most recent ventricular signal resulting from a most recent pacing pulse (see col. 11, ln. 37-41), and comparing at least one morphological characteristic of a past ventricular signal to the same morphological characteristic of the current ventricular signal (see col. 3, ln. 9-11). Finally, the Examiner takes the position that it is inherent that the device of Van Dam utilizes a past ventricular signal where the heart is fully captured by the past pacing pulse. It is necessary for a pacing pulse to fully capture the heart in order to evoke a cardiac response that generates the QT interval of Van Dam. Furthermore, it is inherent that when the device of Van Dam extends the pacing interval between pacing pulses, thus increasing the amount of time between pulses, the detection of intrinsic ventricular activity is aided. If there is a longer period of time during which there is no pacing pulse, the possibility of detecting intrinsic ventricular activity is enhanced.

16. Regarding claims 35 and 54, it is inherent that the subsequently delivered pacing pulse of Van Dam may be delivered to a ventricle of the heart after the delivered pacing pulse (see col. 4, ln. 19-21).

17. Regarding claims 40, 49, and 59, Van Dam discloses that a morphological characteristic that may be used is a T-wave amplitude or T wave slope (see col. 3, ln. 9-11).

18. Regarding claim 50, Van Dam discloses memory 59 which may be used to store the past ventricular signal (see Figure 5).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

19. Claims 33-36, 38, 40-45, 47, 49-55, 57, and 59-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Bradley (U.S. 2003/0050671). Regarding claims 33, 36, 38, 41, 42, 45, 47, 51, 52, 55, 57, 60, and 61, Bradley discloses a method and apparatus for capture tracking that includes at least one electrode 26, 32, 34, 36 to deliver a ventricular pacing pulse and sense a ventricular signal response and a processor 60 (see Figures 1 and 2). Further, Bradley discloses that the processor detects whether an autonomous intrinsic signal component is present within the sensed ventricular response by comparing a morphological characteristic of a past signal response to the same morphological characteristic of the sensed response (see Abstract) and extends a pacing interval in response to the detecting of an autonomous intrinsic signal component (see Figures 5 and 6). Further, Bradley discloses modulating a pacing interval to aid in the detection of the autonomous intrinsic signal component (see paragraph 64).

20. Regarding claims 34, 43, and 53, Bradley discloses modulating an atrial to ventricular pacing delay to aid in the detection of the autonomous intrinsic signal component (see paragraph 64).

21. Regarding claims 35, 44, and 54, Bradley discloses that the subsequently delivered pacing pulse may be delivered to a ventricle (see Figures 5 and 6 and paragraph 40).
22. Regarding claims 40, 49, and 59, Bradley discloses that the morphological characteristic may be amplitude (see paragraph 100) or slope (see paragraph 72).
23. Regarding claim 50, Bradley discloses a memory 94 (see Figure 2).

Response to Arguments

24. Applicant's arguments filed November 6, 2009 have been fully considered by the Examiner. The arguments are not persuasive. Regarding the rejection of claims 41, 51, and 60 as being indefinite for using the term "deviates enough", the Applicant argues that the claims clearly state that sufficient deviation is clearly defined as exceeding a threshold. However, as discussed above with respect to this rejection, neither the claim, nor the specification, indicate what would be a sufficient deviation for the pacing pulse from the morphological characteristic of the past ventricular signal to exceed a threshold. The claim and the specification both fail to describe such a threshold or suggest an appropriate value for such a threshold. As such, it is unclear what would constitute enough of a deviation to satisfy such claim limitations. Therefore, the Examiner considers the rejection to stand.
25. Regarding the rejection of the claims as being anticipated by Van Dam, the Applicant argues that "Van Dam never determines if the T-wave, or any other portion of a signal following a pacing pulse, represents intrinsic activity present in the sensed ventricular signal response to the delivered pacing pulse." The Examiner respectfully disagrees. Van Dam discloses at col. 11, ln. 54-67 detecting whether the T-wave is an

intrinsic T-wave. As such, Van Dam discloses the invention as claimed. Further, the Applicant argues that Van Dam fails to teach modulating a pacing interval to aid in detecting whether an autonomous intrinsic signal component is present. The Examiner respectfully submits that Van Dam teaches modulating a pacing interval at step 210 shown in Figure 6.

26. Regarding the rejection of the claims as being anticipated by Bradley, the Applicant argues that Bradley fails to teach modulating a pacing interval that the ventricular pacing pulse is delivered at to aid in detecting whether an autonomous intrinsic signal component is present within the heart. The Applicant submits that paragraph 64, previously cited in the Office Action, teaches adjusting pacing parameters in response to physiological sensors and thus the parameters are set according to a state of the patient. While the Examiner does not acquiesce to the Applicant's characterization of Bradley, the Examiner submits that the Applicant's arguments against such a characterization do not appear to be based on the claim language. The claims currently require a variation of "modulating a pacing interval that the ventricular pacing pulse is delivered at to aid in detecting whether an autonomous intrinsic signal component is present within the heart." The claims do not specify that such modulation is to be carried out in response to anything. Therefore, the Applicant's arguments appear to be directed against that which is not claimed. As such, the Examiner respectfully submits that Bradley discloses the invention as claimed.

Conclusion

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMMIE HELLER whose telephone number is (571)272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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